



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0268]

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug

Administration: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration.” The document provides guidance to industry on how to label bottled or otherwise packaged beers that are subject to FDA’s labeling laws and regulations. This guidance is being issued in light of the ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly the Bureau of Alcohol, Tobacco, and Firearms) (TTB Ruling 2008-3, dated July 7, 2008) clarifying that certain beers do not meet the definition of a “malt beverage” under the Federal Alcohol Administration Act (FAA Act). Because these beers are not subject to the labeling provisions of the FAA Act, they are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit electronic comments on the guidance to <http://www.regulations.gov>.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling and Dietary

Supplements, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of August 17, 2009 (74 FR 41438), we announced the availability of a draft guidance entitled “Guidance for Industry; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request” and gave interested parties an opportunity to submit comments on the draft guidance at any time and comments on the proposed collection of information by October 16, 2009. We received one comment which we reviewed and evaluated. On our own initiative, we added a reference to the nutrition labeling requirements for certain beers and other alcohol beverages served in restaurants or similar retail food establishments, under FDA’s final rule for menu labeling which appeared in the Federal Register on December 1, 2014 (79 FR 71156). We also clarified that the guidance pertains to bottled or otherwise packaged beers subject to our jurisdiction. We are issuing the guidance with no substantive changes.

The final guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on the labeling of

certain bottled or otherwise packaged beers subject to our jurisdiction. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0728.

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA guidance document using FDA's Web site listed previously to find the most current version of the guidance.

## V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. TTB Ruling 2008-3, July 7, 2008, available at:

<http://www.ttb.gov/rulings/2008-3.pdf>.

2. Memorandum of Understanding 225-88-2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at:

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm>

Dated: December 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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